

## REMARKS/ARGUMENTS

### **Telephonic Interview**

Applicant expresses his gratitude to the Examiner for the courtesies extended to Applicant's undersigned representative during the telephonic interview conducted on April 3, 2007. During the interview the Examiner was asked for the basis for concluding that Table 1 and the phrase "350 - 450 Dalton MW" in the Claims were New Matter, and to explain why she thought the phrase "MW fraction of a natural extract" in the Claims was unclear or confusing. Examiner indicated she would ask her supervisor for the answers to these questions and would get back to Applicant's representative with his answers. These questions were not answered and no agreement was made on the Claims.

### **Election/Restrictions**

The Examiner has withdrawn from consideration Claims 51 - 56 as being directed to an invention that is independent or distinct from the invention originally claimed because they are directed to a non-elected invention. The election was Group I and the species, palm extract, in the reply filed on July 21, 2005.

Applicant disagrees with the Examiner's conclusion since claims 51 - 56 pertain to elected Group I and species – palm extract. Group I is "drawn to a composition comprising annatto extract". Claims 51 - 56 are annatto extract compositions. Claims 54 and 56 are Markush claims that include the species "palm extract", which is the elected species. Therefore, claims 51 - 56 are claims within the elected Group I and species – palm extract.

The Examiner is requested to remove the objection to these claims and examine the claims on their merit. Applicant believes Claims 51 - 56 are allowable and respectfully asks the Examiner to allow these claims.

### **Specification**

The Examiner has objected to the amendment filed January 2, 2007 under 35 U.S.C. 132(a) because she alleges that it introduces new matter into the disclosure. She stated "35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the

invention. The added material which is not supported by the original disclosure is as follows: see newly added Table 1.”

The Applicant disagrees with the Examiner that Table 1 enters New Matter, since the contents of this table was supported by the Original disclosure as filed. Not all material added to a Specification is New Matter and there are situations where the addition of material to the Specification is not only allowed but required.

Form Paragraph 6.19 states in part:

*“The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office ...”* [emphasis added]

The insertion of Table 1 and the following descriptive paragraph is not New Matter. The MPEP describes several situations where material is allowed to be added to the Specification, and at least one of these situations allows the insertion of Table 1 and the following descriptive paragraph. Three of the justifications for allowing the insertion of material in the Specification are described below.

1. The material was originally in the Patent Application when filed.

Table 1 lists the molecular weights of the various forms of tocopherol and tocotrienol [alpha-, beta-, gamma-, and delta-] disclosed in the application.

*Table 1. Molecular weights*

	<i>Tocopherol</i>	<i>Tocotrienol</i>
<i>Alpha</i>	430	424
<i>Beta</i>	417	411
<i>Gamma</i>	417	410
<i>Delta</i>	403	396

The “application at filing” included a Preliminary amendment to include the following statement:

*“[0002] All publications, patents, patent applications, databases and other references cited in this application, all related applications referenced herein, and all references cited therein, are incorporated by reference in their entirety as if restated here in full and as if each individual publication, patent, patent application, database or other reference were specifically and individually indicated to be incorporated by reference.”*

The pertinent section of the MPEP states:

***2163.07(b) Incorporation by Reference***

*“Instead of repeating some information contained in another document, an application may attempt to incorporate the content of another document or part thereof by reference to the document in the text of the specification. The information incorporated is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed. Replacing the identified material incorporated by reference with the actual text is not new matter. ..”* [emphasis added]

Applicant in the Response to the Non-Final Rejection cited the specific document incorporated by reference, and gave the page, paragraph and line for the location of each molecular weight. Merely rephrasing or tabulating of a portion of the specification does not constitute New Matter. Additionally, Applicant submitted an Appendix with the Response that contained a copy of the specific page showing the material incorporated by reference. A copy each document that was incorporated by reference had been submitted with an IDS and the copies in the Appendix had been obtained from the IFW of the application.

**2. The material was inherent**

The pertinent section of the MPEP states:

***2163.07(a) Inherent Function, Theory, or Advantage***

*“By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application*

*necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter.*“ [emphasis added]

The Specification “as filed” discloses the various forms of tocopherol and tocotrienol [alpha-, beta-, gamma-, and delta-] using standard chemical terminology. The molecular weight of a chemical is an inherent quality of that chemical, and it is specific and unchanging. For example, if sodium chloride was disclosed, the formula (NaCl) and molecular weight (Na = 23 and Cl = 35) are inherently disclosed by this disclosure.

Therefore, the disclosure of a chemical by use of standard chemical terminology inherently discloses its chemical structure, chemical formula and molecular weight.

3. The material was common knowledge to a person skilled in the arts and its presence was not required by Patent Law.

Form Paragraph 6.02 states in part:

***6.02 Content of Specification***

***(i) DETAILED DESCRIPTION OF THE INVENTION***

*“...The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described, and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail.”*

In the Response to the Non-Final Rejection, Applicant submitted a Declaration by Tan (Appendix 1), which is again submitted to show that a person skilled in the arts would know the molecular weights of the various forms of tocopherol and tocotrienol [alpha-, beta-, gamma-, and delta-] disclosed in the application.

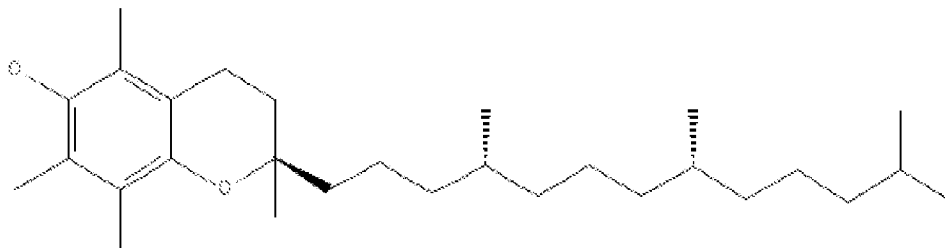
The Tan declaration (Appendix 1) states in part:

*“.. a person having ordinary skill in the arts would be able to calculate the molecular weights of the isomers of tocopherol and tocotrienol from their chemical structures as:*

*Alpha-Tocopherol = 430, Beta-Tocopherol = 417, Gamma-Tocopherol = 417, Delta-Tocopherol = 403, Alpha-Tocotrienol = 424, Beta-Tocotrienol = 411, Gamma-Tocotrienol = 410, and Delta-Tocotrienol = 396.”*

The various forms of tocopherol and tocotrienol disclosed in the application are disclosed using standard chemical terminology. A “person having ordinary skill in the arts” would know both the chemical structure and chemical formula of each form of tocopherol and tocotrienol.

For example, alpha-tocopherol has a chemical structure of



This chemical structure gives the chemical formula of  $C_{29}H_{50}O_2$ . The molecular weights of Carbon (12), Hydrogen (1) and Oxygen (16) are learned in Grade School and are known by children as young as 10 years old (5<sup>th</sup> Graders) as can be seen on a current TV Game Show.

The molecular weight of alpha-tocopherol is easy to calculate by simple math. The molecular weight of  $C_{29}H_{50}O_2 = (29 * 12) + (50 * 1) + (2 * 16) = 358 + 50 + 32 = 430$ .

In light of the foregoing arguments, cited MPEP sections and corresponding Patent Laws, the Examiner is respectfully requested to remove the New Matter objection to Table 1.

In the interests of compact prosecution, in the event the Examiner still believes that Table 1 is New Matter, she is requested to state why the molecular weights in Table 1 are not either present in the Application as filed, inherent qualities of the disclosed various forms of tocopherol and tocotrienol disclosed in the application or common knowledge to a person skilled in the arts.

## Claims

### 35 U.S.C. § 112 Rejections

Claims 39, 47 and 49

The Examiner has rejected Claims 39, 47 and 49 under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement. The Examiner has stated “the claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.” Specifically the Examiner has alleged that the recitation “a 350-450 Dalton MW fraction of” in the claims is New Matter.

Applicant disagrees with the Examiner’s conclusion that the phrase “a 350-450 Dalton MW fraction of” in the Claims is New Matter. Applicant has stated above in the discussion concerning the Examiner’s rejection of Table 1 as New Matter, that this material is not New Matter. Applicant has stated at least three reasons why this material is not New Matter. First, the molecular weights of the various forms of tocopherol and tocotrienol were present in the Application as filed; second, the molecular weight of a chemical is an inherent quality of that chemical; and third, the molecular weights of the various forms of tocopherol and tocotrienol are common knowledge to a person skilled in the arts.

In light of the foregoing arguments, cited MPEP sections and corresponding Patent Laws, the Examiner is respectfully requested to remove the New Matter objection and examine Claims 39, 47 and 49 on their merit.

In the interests of compact prosecution, in the event the Examiner still believes that the phrase “a 350-450 Dalton MW fraction of” in the claims is New Matter, she is requested to state why support for this feature was not either present in the Application as filed, inherent qualities of the disclosed various forms of tocopherol and tocotrienol disclosed in the application or common knowledge to a person skilled in the arts.

Applicant believes Claims 39, 47 and 49 are allowable and respectfully asks the Examiner to allow these claims.

### Claims 39, 47 and 49

The Examiner has rejected Claims 39, 47 and 49 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner has stated that the phrase “fraction of a natural extract” in claims 39, 47 and 49 is indefinite because it is not clear what is encompassed by this recitation. The Examiner asks “How can there be a “fraction” of an extract?”

The Applicant disagrees with the Examiner. The Examiner has truncated the phrase to exclude important words. The complete phrase is “MW fraction of a natural extract”. The meaning of this phrase is readily understood by any college level person who has studied Biochemistry or Chemistry, and would be known by a “person having ordinary skill in the arts”.

The definition of a “natural extract” has already been given in two previous Responses to Office Actions.

The term “MW (molecular weight) fraction” refers to that part (fraction) of a substance (i.e., natural extract) that has chemicals of that molecular weight. A standard analytical tool in Biochemistry or Chemistry is the separation of a substance into its various individual chemicals by their molecular weight. Typical methods include column chromatography, HPLC, and SDS-PAGE. Each of these analytical tools will separate a complex substance (i.e., natural extract) so the individual chemicals will travel at different rates through the medium (e.g., sepharose beads or polymerized gels). In the case of column chromatography or HPLC, the carrier solution is collected (e.g., test tubes) as it comes off the column into “fractions”. There is a detector on the end of the column which detects the presence of material. The detector charts the “peaks” and the corresponding fraction that contains this material. The molecular weights of these peaks can be calculated using standards with known molecular weights (e.g., Keyhole Limpet Hemocyanin).

Therefore, “a person skilled in the arts” would readily understand the meaning of “molecular weight fraction of a natural extract”. As an example of the common use of this phrase, a GOOGLE search of the phrase “molecular weight fraction” returns 137,000 hits.

In light of the foregoing arguments, the Examiner is respectfully requested to remove the 35 U.S.C. 112, second paragraph, rejection and examine Claims 39, 47 and 49 on their merit. Applicant believes Claims 39, 47 and 49 are allowable and respectfully asks the Examiner to allow these claims.

## Claims 47 and 49

The Examiner has noted that the term “comprsing” is misspelled in Claim 47. Applicant noticed a similar misspelling in Claim 49.

Applicant has amended Claims 47 and 49 to correct the misspelling. In light of the foregoing amendment, the Examiner is respectfully requested to remove the 35 U.S.C. 112, second paragraph, rejection and examine Claims 47 and 49 on their merit. Applicant believes Claims 47 and 49 are allowable and respectfully asks the Examiner to allow these claims.

## 35 U.S.C. §103 Rejections

### Claims 1, 25, and 37 - 50

The Examiner has rejected Claims 1, 25, and 37 - 50 under 35 U.S.C. 103(a) as being unpatentable over Tan (US 6,350,453) in view of Wright (US 5,217,992) further in view of Meijer et al. (US 6,787,151).

Applicant disagrees with the Examiner’s conclusion that the cited patents, either individually or in combination, disclose all the features in Claims 1, 25, and 37 - 50. Additionally, the Examiner has incorrectly described the disclosed distillation process in Tan (‘453). The distillation process does not disclose “an oily byproduct extract of *Bixa orellana* seed and a 350 - 450 Dalton MW fraction of a natural extract”.

The Tan Declaration (Appendix 1) states:

*“The Rice bran oil used in the experiment was cooking oil. Vegetable cooking oils and animal fats have molecular weights typically in the 800 - 900 Dalton range, or more broadly a range of 500 - 1000 Daltons..”* (paragraph 9).

However, the Applicant does agree with the Examiner that “Tan does not disclose wherein the amounts are disclosed for the tocotrienols and tocopherols or wherein palm oil is specifically use together with the *Bixa orellana* extract.”

Tan (‘453) does not disclose a ratio of delta-tocotrienol to gamma-tocotrienol within the range (1:25 to 8:1 and 10:1 to 25:1) of Claim 1. Wright (‘992) and Meijer (‘151) do not disclose any delta:gamma ratios, nor do they disclose any of the ingredients listed in Claim 25.



Therefore, the combination of Tan ('453), Wright ('992) and Meijer ('151) do not disclose all the features in these claims.

The Examiner has listed numerous “beneficial” results disclosed in Wright ('992) and Meijer ('151) that may result from the ingestion of Vitamin E. It should be noted that the claims are to a “composition” and do not make any claims to “beneficial” results. MPEP 2145(VI) states “Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.”

The Examiner has stated “one of ordinary skill in the art would have been motivated to combine *Bixa orellana* (i.e. annatto) oil byproduct and a palm oil extract (i.e. natural extract) because of the beneficial properties that tocotrienols have in decreasing blood levels and the various types of tocotrienols would be inherent to the extract.”

First, it should be noted that there is no evidence that the claimed delta:gamma ratios are inherent in either unprocessed annatto seed or *Bixa orellana* (i.e. annatto) oil byproduct. In fact, the evidence is to the contrary. The Tan Declaration (Appendix 1) states the inherent delta:gamma ratio is 9:1 (paragraph 7).

One of the factual inquiries in the consideration and determination of obviousness under 35 U.S.C. 103 is the evaluation of evidence of secondary considerations (*Graham v. John Deere Co.*). MPEP 2141 lists some of these secondary considerations as commercial success, long felt but unsolved needs, and failure of others.

The patents of Wright ('992) and Meijer ('151), and the Examiner's failure to find any patents, published publications or products with the claimed ratio of delta-tocotrienol to gamma-tocotrienol is evidence of Non-obviousness. Additionally, it should be noted that the only products being sold with the claimed ratios are either by the Applicant's company or by a company with a license from the Applicant's company. These three facts demonstrate commercial success of the claimed product, a long felt but unsolved need by other people, and the failure of others to produce a product with these ratios.

The claimed compositions contain delta-tocotrienol and gamma-tocotrienol obtained from “an oily byproduct of *Bixa orellana* seed”. Making a product with a ratio of delta-tocotrienol to gamma-tocotrienol not found in nature is not simply a matter of taking bottles off a shelf and mixing any ratio desired. It is first a matter of obtaining a product with a ratio that alone or in combination with another product can achieve the desired final ratio. If a person does

not have the correct starting material, obtaining a desired final product is impossible no matter how much “motivation to combine”. It is the ability to obtain the claimed ratios of delta-tocotrienol and gamma-tocotrienol that is important. No matter how strong there is of a “motivation to combine”, if it is unachievable, it is not evidence of obviousness.

## **Conclusion**

Claims 1, 25, and 37 - 56 are currently pending. Claims 2-24 and 26-36 are Canceled. Claims 47 and 49 are amended to correct a typographical error.

Applicant has endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims, the reasons therefore, and arguments in support of the patentability of the pending claim set are presented above. In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested and it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

No fees are believed due since this Response is filed within 3 months of the mailing of the Final Rejection. However, please charge any additional fees, including any fees for additional extension of time, or credit overpayment to credit card information.

Date June 3, 2007

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